

UNITED STATES DISTRICT COURT  
DISTRICT OF MINNESOTA

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In re: BAIR HUGGER FORCED AIR  
WARMING PRODUCTS LIABILITY  
LITIGATION

MDL No. 15-2666 (JNE/FLN)

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This Document Relates To:  
*All Cases*

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**PLAINTIFFS' REPLY IN SUPPORT OF MOTION TO EXCLUDE OPINIONS  
AND TESTIMONY OF MICHAEL KEEN**

Fundamentally, the claims plaintiffs have asserted in this MDL boil down to two questions that could potentially relate to the opinions offered by Michael Keen (1) do particles correlate with bacterial load, also known as bioburden, in the air; and (2) does the Bair Hugger system increase the number of particles in the operating room and over the surgical site during an operation?

The answer to the second question is uncontested: 3M admits that every single study done to date, both peer-reviewed studies and internal company testing, demonstrate an increase in particles over the surgical site when the Bair Hugger system is on and set to warm.<sup>1</sup> Keen disclosed opinions on a host of subjects that relate, directly or indirectly, to both of the questions identified above. With a few narrow exceptions, Keen lacks the qualifications to offer expert testimony on those topics.

Keen works in a hospital in Canada. He did not conduct any experiments or testing or simulations or calculations in connection with this case.<sup>2</sup> Keen does not design HVAC systems for operating rooms.<sup>3</sup> Keen does not design products and never has.<sup>4</sup>

Even considering Defendants' response, it would appear that the sole basis for Keen's far-ranging testimony is his membership on a committee of the American Society of Heating, Refrigeration and Air-Conditioning Engineers (ASHRAE). But there remains no indication that his ASHRAE committee membership experience gave Keen anything approaching the level of expertise necessary to support his proffered opinions.

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<sup>1</sup> See Ex. B, Deposition of 3M 30(b)(6) Designee Al Van Duren at 258:5-13. Of course, this key admission was not provided to Michael Keen or the vast majority of the other experts Defendants hope to call in this case.

<sup>2</sup> Ex. D, Deposition of Michael Keen ("Keen Dep.") 44:17-45:24.

<sup>3</sup> Keen Dep. 146:9-12.

<sup>4</sup> Keen Dep. 201:13-23.

To recap, as outlined in Plaintiffs' initial motion papers, Mr. Keen should be precluded from opining in any way on the following topics:

- The safety and efficacy of the Bair Hugger and its filtration system in an operating room, including the air flow generated by a Bair Hugger in operation;
- Filtration requirements for medical devices, including specifically whether the Bair Hugger's intake filter was "an appropriate filter to include in the unit." Keen Rpt. at 23.
- Surgical site infections including the potential sources and/or transmission pathways for such infections, including the potential for Bair Hugger to contribute to such infections;
- Operating room airflow characteristics including the potential disruption of OR airflow caused by staff and other heat- and/or turbulence producing elements and the positive or negative impacts of thermal plumes;
- Movement of particles and bacteria in OR air flows, including the efficacy or validity of techniques used to study such particle movement;
- Migration of bacteria from contaminated Bair Hugger devices into the OR.

## **I. LEGAL STANDARD**

Under Federal Rule of Evidence 702, expert testimony is admissible if a witness is "qualified...by knowledge, skill, experience, training, or education," and if his or her testimony is 1) helpful to the trier of fact in understanding the evidence or determining a fact in issue; 2) "based upon sufficient facts or data"; and 3) "the product of reliable

principles and methods" that 4) have been reliably applied "to the facts of the case." Fed R. Evid. 702.

Expert testimony is reliable only if the expert is qualified to give an opinion and his methodology is scientifically valid and is properly applied to the facts in issue. *Kapps v. Biosense Webster, Inc.*, 813 F. Supp. 2d 1128, 1146 (D. Minn. 2011). Qualifications of a witness are necessarily contextual, such that an expert who is qualified in one field may not necessarily be an expert in a different field. *See Wheeling Pitts. Steel v. Beelman River Terminals*, 254 F.3d 706, 716 (8th Cir. 2001) (reversing district court's admission of testimony where expert was qualified in one subject matter but not qualified by "knowledge, skill, experience, training, or education" in another subject area).

## II. ARGUMENT

### A. Mr. Keen Is Not Qualified To Give Expert Testimony As To The Selection, Design, or Efficacy Of The Bair Hugger Intake Filter

Mr. Keen lacks the qualifications to offer an opinion on the appropriateness of the intake filter on 3M's Bair Hugger. To offer testimony under Rule 702, a witness must qualify as an expert in a field based on his or her "knowledge, skill, experience, training, or education." Keen proposes to testify that the filtration standard for an operating room HVAC system should be applied to a medical device.

Keen is not qualified as an expert on medical device design, much less the selection of a filter or design of a filtration system for a medical device. Mr. Keen's report does not cite any studies, standards, or authorities for designing or evaluating filtration requirements for medical devices. He merely grafted a standard that applies to

operating room design and construction (ASHRAE 52.2) onto a medical device. In deposition, Keen admitted that the ASHRAE standards do not apply to medical devices.<sup>5</sup> Keen admitted he has no experience in designing a medical device.<sup>6</sup> He admitted he has no knowledge of filtration standards for medical devices.<sup>7</sup> Keen has never designed a filter for a medical device.<sup>8</sup> *Id.*

Given Keen's lack of knowledge, skill, experience, training, or education in designing medical devices or filtration systems for medical devices, he is not "qualified as an expert" within the meaning of Rule 702 to offer any testimony related to the Bair Hugger or its use in an operating room. This Court should exclude any testimony from Mr. Keen as to the safety and efficacy of the Bair Hugger unit or its filter and in particular, his opinion that the Bair Hugger's intake filter was "an appropriate filter to include on the unit."

**B. Keen Is Not Qualified to Give Expert Testimony As To Operating Room Design or Airflow Characteristics**

Keen seeks to offer testimony about air flow and thermal loads in operating rooms and the potential benefits of thermal plumes. Keen is not qualified to offer such testimony. The bulk of his experience with his hospital has been in an advisory and administrative, not a design, capacity.<sup>9</sup> When questioned on his background in engineering and operating room design at his deposition, Mr. Keen testified that he had never designed an HVAC system for an operating room on his own and would not be

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<sup>5</sup> Keen Dep. at 322:23-25.

<sup>6</sup> Keen Dep. at 61:12-15, 323:1-4.

<sup>7</sup> *Id.* at 324:2-6.

<sup>8</sup> *Id.*

<sup>9</sup> See Ex. C, Keen CV.

comfortable designing one on his own.<sup>10</sup> Further, he has only participated in the design of one United States operating room, and that was more than twenty years ago.<sup>11</sup> Keen does not hold himself out as an expert in operating room air flow and has never personally performed particle measurement.<sup>12</sup>

In responding to Plaintiffs' motion to exclude Mr. Keen's testimony and opinions, 3M argues Mr. Keen is qualified because he sits on a committee with the author of a letter to the editor (Def. Opp. at 11).<sup>13</sup> The Court could likely take judicial notice that co-chairing a committee – even with a qualified expert - does not an expert make. Rule 703 does not allow an expert in one field to merely parrot the opinions of a different expert, especially where the creation of the data required the use of professional discretion in a disparate discipline. *See Dura Automotive*, 285 F.3d at 613. Because Mr. Keen does not meet the Rule 702 requirements to be qualified as an expert on these subjects, they should be excluded from his testimony.

### C. **Keen Is Not Qualified To Testify About Particle Flow Studies**

Keen criticizes the accuracy of particle tracking studies using neutrally-buoyant bubbles. This testimony should be excluded because Keen is not qualified as an expert in this subject matter. Keen has never personally conducted experiments or tests of particle

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<sup>10</sup> Keen Dep. 145:15-17; 146:9-12; 294:10-13.

<sup>11</sup> Keen Dep. at 148:24-25; 294:23-295:2.

<sup>12</sup> *Id.* at 282:18-283:12; 268:1-12.

<sup>13</sup> Defendants' misrepresent the nature of Dr. Memarzadeh's writing as well, asserting Memarzadeh performed "computational fluid dynamics research [...] for the [National Institute of Health]" when in actuality the writing in question is a Letter to the Editor – not a peer reviewed publication, written by Dr. Memarzadeh, but not in his capacity as head of the NIH either. The neither the underlying data nor the research referenced in this Letter to the Editor have ever been published, much less peer-reviewed. The opposition briefs are replete with these kinds of mischaracterizations that go well beyond advocacy and rather, tread towards violation of duty of candor to this tribunal.

sampling.<sup>14</sup> Prior to his work on this case, Keen had never considered the use of neutrally buoyant bubbles in tracing or simulating particle flow.<sup>15</sup> Mr. Keen was unable to give any specific comparisons of the densities of bubbles as opposed to particles in the air.<sup>16</sup> Keen testified he would defer to particle physics experts on issues related to particle physics, including principles of how particles settle over time.<sup>17</sup> Mr. Keen has never done any particle measuring and has never used or been trained to use any of the tools that are used to measure particles in the air.<sup>18</sup> Due to his lack of training and experience, Mr. Keen admitted that he is not able to offer any testimony on the accuracy of such particle measuring equipment.<sup>19</sup>

Mr. Keen has not disclosed any knowledge, skill, experience, training, or education that would qualify him to criticize the use of neutrally-buoyant bubbles in particle flow analysis as described in peer-reviewed journals. As such, his testimony on those topics is not admissible under Rule 702 and should be excluded.

**D. Keen Is Not Qualified to Testify About the Risk of Infection During Surgery**

A central issue in this litigation is whether the Bair Hugger units increase the risk of particles causing surgical site infections. Based on his lack of knowledge, skill, experience, training, or education, Mr. Keen is fundamentally unsuited to opine on that issue.

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<sup>14</sup> Keen Dep. 282:18-283:3.

<sup>15</sup> *Id.* at 285:5-9.

<sup>16</sup> *Id.* at 282:5-13.

<sup>17</sup> *Id.* at 293:8-12, 295:6-13.

<sup>18</sup> *Id.* at 283:1-3; 283:4-12.

<sup>19</sup> *Id.* at 283:13-19.

Mr. Keen, by his own admission, is not a microbiologist and has no training as a microbiologist or aerobiologist.<sup>20</sup> He admitted that he would rely on a microbiologist to quantify the risk to patients from pathogens or particles that carry pathogens, and that he would defer to a particle physics specialist regarding how particles settle over time.<sup>21</sup> Mr. Keen is not an epidemiologist, and testified he would defer to an epidemiologist or microbiologist on the number of particles or pathogens it would take to cause a surgical site infection.<sup>22</sup> Further, he admitted that he would defer to an infectious disease specialist or microbiologist regarding the ability of a particle to carry bacteria.<sup>23</sup>

Given Mr. Keen's testimony that he lacks experienced and would have to defer to epidemiologists, microbiologists, and particle physics specialists regarding issues related to particles, pathogens, and other contaminants moving through the surgical area and their relation to the Bair Hugger and surgical site infections, none of his testimony in those areas is admissible. Therefore, the court should exclude the portions of Mr. Keen's report that deal with the number of particles or pathogens present in or attributable to a Bair Hugger unit in the operating room and any effects they might have on increasing the risk of infection.

**E. Mr. Keen Should be Prohibited from Offering Any Testimony About Bair Hugger Operation of Air Flows**

Mr. Keen has never evaluated a Bair Hugger in operation as it would be during surgery, yet he offers opinions on the operating of the device and its resulting air flows in

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<sup>20</sup> *Id.* at 165:5-10.

<sup>21</sup> *Id.* at 179:19-24; 288:10-12; 295:6-296:2.

<sup>22</sup> *Id.* at 299:24-300:8; 300:11-19.

<sup>23</sup> *Id.* at 287:25-288:5; 290:24-291:5.

his report. Because Mr. Keen has no valid basis for those opinions, they should be excluded.

To try to understand how Bair Hugger works in the operating room, Mr. Keen testified that he relied, perhaps solely, on YouTube videos. Relying on YouTube videos of unknown origin to assist in preparing his expert report is not a reliable methodology, particularly given Mr. Keen was unable to identify the videos.<sup>24</sup> Mr. Keen's failure to provide accurate citation or other identifying information relating to the videos precludes the Plaintiffs from examining them or providing them to Plaintiffs' experts for evaluation and potential cross-examination of Mr. Keen.

3M bears the burden of demonstrating that Mr. Keane's reliance on other data is "reasonable" before his testimony can be admitted. Federal Rule of Evidence 703. Here, where 3M's expert either cannot point to the source of the information upon which his opinions are based, or admits that his opinions were based solely on watching a video that 3M posted on the internet in response to proceedings in this litigation, 3M surely cannot meet that burden. The Court should exclude any testimony or opinions based on Keen's unreliable methods and lack of qualifications.

#### **F. Keen's Testimony on Bair Hugger Filter Tests Should Be Excluded**

Keen's report contains bare-bones descriptions of tests that were allegedly performed on what he describes as "Bair Hugger Filters." Mr. Keen did not perform the tests himself. *See* Keen Rpt. at 8. The testing was performed in April of 2016, well after this litigation was initiated. *Id.* Keen offered no description of the conditions under which

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<sup>24</sup> *Id.* at 117:17-118:6; 222:8-225:3; 227:2-229:6; 252:2-19.

the testing occurred that would demonstrate that the testing was conducted in a reliable fashion. *Id.* He offers no basis on which to testify that the products tested were, in fact, filters for the Bair Hugger devices he claims them to be. *Id.*

All the information Keen received about these filter tests was provided by counsel for 3M. His report merely describes the content of an out of court test conducted by an unknown third party at the behest of 3M's litigation counsel. Keen has no direct experience, made no effort to validate the experimental protocol, the source of the filters, or even that they were representative of current *or* past Bair Hugger Filters. Given the complete absence of information by which the methodology used for testing could be deemed reliable, Keen's testimony regarding this testing should be excluded.

**G. Neither *Daubert* nor *Frye-Mack* Require General Acceptance of an Experts' Opinions**

In their response, Defendants argue "in addition to foundational reliability, Minnesota law further requires that an expert's opinions are generally accepted in the relevant scientific community." (Def. Opp. at 13)(emphasis added). But neither *Daubert* nor *Frye-Mack* require general acceptance of an expert's *opinions*; the rules and case law require generally accepted *methodology* in arriving at the proffered opinions. If that were not the case, there would be no opinion testimony offered in state or federal courts, as admissible testimony would be limited to uncontroverted facts. Neither science, medicine, nor law takes such an limited view of the range of admissible testimony. The Court should disregard Defendants' incorrect statement of law.

### III. CONCLUSION

For the reasons stated above, Plaintiffs ask the Court to Exclude the Deficient Portions of the Testimony of Michael Keen.

Respectfully submitted,

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CIRESI CONLIN L.L.P.

/s/Michael V. Ciresi

Michael V. Ciresi (MN #0016949)  
Jan M. Conlin (MN #0192697)  
Michael Sacchet (MN # 395817)  
Ciresi Conlin LLP  
225 S. 6th St., Suite 4600  
Minneapolis, MN 55402  
Phone: 612.361.8202  
Email: MVC@CiresiConlin.com  
JMC@CiresiConlin.com  
MAS@ciresiconlin.com

MESHBESHER & SPENCE LTD.

/s/ Genevieve M. Zimmerman

Genevieve M. Zimmerman (MN #330292)  
1616 Park Avenue South  
Minneapolis, MN 55404  
Phone: (612) 339-9121  
Fax: (612) 339-9188  
Email: gzimmerman@meshbesher.com

LEVIN PAPANTONIO, P.A.

/s/ Ben W. Gordon, Jr.

Ben W. Gordon (FL # 882836) – *Pro Hac Vice*  
J. Michael Papantonio (FL # 335924)  
316 S. Baylen Street, Suite 600  
Pensacola, FL 32502-5996  
Phone: (850) 435-7090  
Fax: (850) 436-6090  
Email: bgordon@levinlaw.com

*Plaintiffs Co-Lead Counsel*